REMARKS

Claims 10-21 are pending. By this Amendment, claims 10, 17, and 18 are cancelled, claims 11-13 are amended and new claims 22-25 are added. Support for the amendments can be found throughout the specification and figures as originally filed, and no new matter has been added.

Claim Rejections – 35 U.S.C. § 103

Claims 10 and 17 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 6,911,042 to Weadock in view of U.S. Patent No. 5,897,572 to Schulsinger et al., claims 11-12 and 21 stand rejected under § 103(a) as being unpatentable over Weadock in view of Schulsinger et al. as applied to claim 10, and further in view of U.S. Patent No. 5,397,355 to Marin et al., claims 14 15, and 21 stand rejected under § 103(a) as being unpatentable over Weadock in view of Schulsinger et al. and Marin et al. and further in view of U.S. Patent No. 7,022,131 to Derowe et al., claim 16 stands rejected under § 103(a) as being unpatentable over Weadock in view of Schulsinger et al. and Marin, et al. and further in view of U.S. Application Publication No. 2003/0120338 to Chobotov et al., claims 19-20 stand rejected under § 103(a) as being unpatentable over Weadock in view of Schulsinger et al., Marin et al., and Chobotov et al. and further in view of U.S. Patent No. 6,241,741 to Duhaylongsod et al., and claim 18 stands rejected under § 103(a) as being unpatentable over U.S. Patent No. 5,941,908 to Goldsteen et al. in view of Weadock, further in view of Schulsinger et al., and further in view of Derowe et al.

In order to advance prosecution, new independent claims 22-25 have been added to clarify that embodiments of the present invention are directed to an independent, stand alone,

single device for connecting previously intubed ends of a body duct and a prosthesis which ensures a tight, safe and secure link of the connecting device without any risk of post surgical bleeding, and that may be used over an extended range of body duct diameters. The connection device, or tubular mesh sleeve, as recited in claims 22-25, is adapted to be "positioned *within an interior* of the prosthesis proximate the first end of the prosthesis," wherein the first end of the prosthesis is intubated in the body duct. The connection device includes a plurality of transfixion pins that have "a hemostatic profile comprising a circular base section extending to a trihedral-shaped end portion whereby hemostasis is achieved at transfixion sites formed by the transfixion pins in the wall of the body duct" as recited in claims 22-25. None of the cited references, taken alone or in any combination, disclose or suggest at least one or more of these limitations in combination with the other limitations of each independent claim.

Weadock discloses an anastomotic coupler 20 which includes a tubularly shaped structure 22 consisting of cells 24 which allow for radial expansion and forming a compliant annular body. Attached to the opposite ends 24, 26 of the annular compliant body 22 are vessel or graft engaging elements, such as axially and outwardly bent staples 28, 30 which are spaced around the periphery of the body structure 22. *See* Fig. 2 and Col. 5, lines 21-36. As disclosed in Weadock, "FIG. 3...illustrates the upper end portion 32 of the vascular graft or endoprostheses 10 (or 18) with the anastomotic coupler 20 positioned *thereover* and having the end of the graft everted such that the staples 28 at the one end 24 of the coupler 20 pierce engagingly through the graft and the wall of the aorta 36..." Col. 5, lines 36-41 (emphasis added). Unlike the device recited in claims 22-25, the coupler 20 of Weadock is not "positioned within an interior of the prosthesis," but rather over the end of the graft.

Weadock discloses the use of a tubularly shaped structure having attached to its opposite ends axially and outwardly bent staples. As illustrated in Figs. 2-4, the staples 28, 30 have a bottom portion extending longitudinally *in a parallel direction* with the longitudinal axis of the body structure, rather than "at least a bottom portion extending longitudinally in an outward and substantially perpendicular direction from an external surface of the mesh sleeve" as recited in new claims 22-25. Moreover, the staples 28, 30 of Weadock are clearly not aligned at "substantially regular intervals about a circumference" of the tubularly shaped structure, as recited in new claims 22-25.

Additionally or alternatively, Applicant respectfully submits that "compliance" in the medical field is defined as "a measure of the ease with which a structure or substance may be deformed." *See, for example*, The American Heritage Medical Dictionary, Houghton Mifflin Co. (2004). The expression in Weadock at col. 5, lines 20-25 of a "compliant annular body" is an annular body that is capable of radial expansion under particular conditions such as a deformation, and does not have a "second after-expansion configuration that is also stable" that is distinct from its initial stable configuration, as recited in new claims 22-25.

Further, Weadock only discloses the use of staples, rather than transfixion pins having a "hemostatic profile comprising a circular base section extending to a trihedral-shaped end portion." Hemostasis is defined as arresting or stopping of bleeding or blood circulation. Therefore, the function of the profile of the transfixion pins as claimed is to stop or inhibit the bleeding at transfixion sites in the wall of the body duct created by the transfixion pins. The staples of Weadock would likely not achieve this function.

None of the other cited references make up for the deficiencies of Weadock described above. Schulsinger et al. is cited for disclosing a needle having a circular portion extending to a trihedral-shaped end portion thereby reducing trauma to the tissue being penetrated as the cutting edge 16 creates a cleaner incision with less tearing of the tissue. Col. 2, lines 25-28. The needle of Schulsinger et al. enables penetration of the tissue and cutting of said tissue during penetration, but the needle does not remain in the tissue after penetration, and therefore would likely not achieve hemostasis.

Marin et al. is cited for disclosing a diamond-shaped mesh structure an arrangement of the barbs on an endoluminal graft connector. Derowe et al. is cited for disclosing that not all spikes of the coupler of the mesh sleeve in Derowe et al. have the same cross section and/or sharpness and/or tip shape and/or have different bending locations. Chobotov et al. is cited for disclosing a design in which the length of each barb can vary within a single device. Duhaylongsod et al. is cited for disclosing barbs 36 attached to the device by either soldering or gluing. Fig. 1A and Col. 4, lines 40-45.

With respect to method claim 25, Goldsteen et al. is cited for disclosing a tubular artificial graft for joining the ends of two separated vessels. The graft has an initially radially relatively small connector structure adjacent each of its ends. As illustrated in Figs. 1 and 3 of Goldsteen et al., the connector structure is located at the extremities of the graft 20, rather "positioned *within an interior* of the prosthesis proximate the first end of the prosthesis," wherein the first end of the prosthesis is intubated in the body duct, as recited in new claims 22-25.

Moreover, "the tissue-piercing structures 36 of the connector structure 30 (see Fig. 5) which radially penetrate the adjacent body tissue structure 10 may be barbed to substantially prevent them from coming out of the tissue they have pierced." Col. 3, lines 44-52. Therefore, the tissue-piercing structures 36 of the connector structures 30 disclosed in Goldsteen et al. do not have a "length sufficient to pass entirely through a wall of the body duct" or "a hemostatic profile comprising a circular base section extending to a trihedral-shaped end portion" as recited in claims 22-25, and would likely not achieve hemostasis.

Further, Goldsteen et al. does not disclose or suggest the limitation of "the first connecting device and an inflatable balloon catheter being introduced into an interior of the prosthesis through a second end of the prosthesis" as recited in claim 25. Rather, Goldsteen et al. teaches to first insert *each axial end* of the graft into the body tissue tubing (col. 2, lines 55-58) and then to introduce balloons initially non-inflated into apertures made in the graft. After removing the balloons, these apertures are closed by tightening and securing purse string sutures (col. 4, lines 40-45), resulting in operating times that can be very long. The method recited in new claim 25 allows for a reduced number of orifices made in the prosethesis to introduce the catheters, thereby preventing or inhibiting weakening of the prosthesis. Moreover, required operating times are reduced since there are less orifices to close, enabling a reduction in mortality risk.

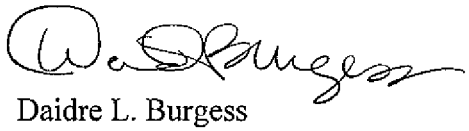
Therefore, it is respectfully submitted that a *prima facie* case of obviousness has not been made at least because all claim limitations have not been considered in judging patentability per MPEP § 2143.03. New independent claims 22-25 are allowable for at least the reasons stated

above. Claims 11-16 and 19-21 depend from claim 22, and are allowable for at least the same reasons claim 22 is allowable.

In view of the foregoing, it is submitted that this application is in condition for allowance. Favorable consideration and prompt allowance of the application are respectfully requested.

The Examiner is invited to telephone the undersigned if the Examiner believes it would be useful to advance prosecution.

Respectfully submitted,



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